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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/403,107	10/14/1999	PETER KUFER	3816-4000	6846

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EXAMINER
HELMS, LARRY RONALD

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 05/07/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/403,107	KUFER ET AL.	
	Examiner	Art Unit	
	Larry R. Helms	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 March 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *18,19,22,28,29,31,32,38,39,42,53-56 and 65-67* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *18-19, 22, 28-29, 31-32, 38-39, 42, 53-56, 65-67* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 18-19, 28 have been amended.

Claims 18-19, 22, 28-29, 31-32, 38-39, 42, 53-56, 65-67 are pending and under examination.

2. The text of those sections of Title 35 U.S.C. code not included in this office action can be found in a prior Office Action.

3. The following Office Action contains NEW GROUNDS of rejection.

Rejections Withdrawn

4. The rejection of claims 18-19, 22, 28-29, 31-32, 38-39, 42, 53-56, 65-67 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in view of the amendments to the claims.

5. The rejection of claims 18-19, 22, 28, 29, 31, 32, 38-39, 42, 53-56, 65-67 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn in view of the amendments to the claims.

Response to Arguments

6. The rejection of claims 22 and 42 under 35 U.S.C. 112, first paragraph, is maintained and made again.

The response filed 3/22/04 has been carefully considured but is deemed not to be persuasive. The response states that both claims 22 and 42 depend from claim 18

and claim 18 states that the antibody comprises both VH and VL and as such has all 6 CDRs (see page 5 of response). In response to this argument, claim 22 has been amended to recite a VH comprising at least one CDR encoded by a portion of nucleotides 1 to 381 of SEQ ID NO:143 and a VL comprising at least one CDR encoded by a portion of 1 to 321 of SEQ ID NO:141. The claim encompasses antibodies which still have either one CDR from the specified sequence and the other CDRs from any unspecified sequence and it would be undue experimentation to determine which if any other CDR sequence to combine with the one specified sequence to obtain an antibody that binds human17-1A. Therefore the specification has not enabled antibodies with one specified CDR sequence and any five CDRs from any other antibody. Therefore the rejection is maintained.

7. The rejection of claims 18-19 under 35 U.S.C. 102(b) as being anticipated by Hoess et al (Proceedings of the American Association for Cancer Research 38page 30 abstract 198, 1997, Ids #3) is maintained.

The response filed 3/22/04 has been carefully considured but is deemed not to be persuasive. The response states that Hoess et al does not teach an antibody that binds to native 17-1A and supports this with a declaration by Dr. Kufer. The declaration has been carefully considured but is deemed not to be persuasive. The declaration states that the title of the abstract is misleading and human antibodies only bound recombinant form of 17-1A and not to cells overexpressing the antigen. In response to this argument, while the title may be misleading, Hoess expressly teaches the human

library and the target of 17-1A and human antibodies directed to the antigen and the library enables one to create high affinity human antibodies for selectively targeting cells overexpressing disease-associated antigens. Thus, Hoess et al teaches how to make antibodies that bind to 17-1A antigen on the surface of the cells.

8. The rejection of claims 18-19, 28-31, 38-39, 53-55, 65, 67 under 35 U.S.C. 103(a) as being unpatentable over Kucherlapati et al (U.S. Patent 6,150,584, filed 10/96) as applied to claims 18-20, 34-40, 43-45, 48-50, 65, 67 above, and further in view of Gottlinger et al (Int, J. Cancer 38:47-53, 1986, IDS #3) is maintained.

The response filed 3/22/04 has been carefully considured but is deemed not to be persuasive. The response states that rejection fails due to the difficulty in creating a human antibody to 17-1A and the human-Ig transgenic mice used carry human-Ig repertoire and this is the same as in humans and this is biased against the 17-1A antigen and even today there is today no human antibody in the literature from the Ig-transgenic mouse and this is stated in the declaration of Dr. Kufer (see page 8 of response). The declaration of Dr. Kufer has been carefully considured but is deemed not to be persuasive. While there may not be any literature report of human anti-17-1A antibodies produced in the Ig-transgenic mice, this is not the standard for a 103 rejection. In addition, while the human Ig-repertoire may be biased this does not mean that one would not have motivation or a reasonable expectation of success to obtain such an antibody. In fact the human library that was used in the instant application was from human blood and bone marrow which would be the same as that used in the

transgenic mouse system. In addition, Kucherlapaty teach many human antigens that can be used and some of these were used for producing human antibodies against human antigens such as those in claim 9 of the patent which can be antigens that are ubiquitous. Therefore, while the repertoire may be biased there would be a reasonable expectation of success to obtain the claimed antibodies.

The following are NEW GROUNDS of rejections

9. Claims 18-19, 22, 28, 29, 31, 32, 38-39, 42, 53-56, 65-67 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claims 18, 28, recite the phrase "as expressed on the surface of cells". The response filed 3/22/04 which amended claim 18 and 28 states that support for the amendment can be found on page 8 and 15 of the specification. The cited pages support the antigen is expressed on the surface of tumor cells not just "cells". The term "cells" is broader and there is no support for the antibody recognizing the antigen on just any cells. Applicants are required to provide specific support for the limitation or remove it from the claims.

Claim Rejections - 35 USC § 103

10. Claims 18-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hoess et al (Proceedings of the American Association for Cancer Research 38 page 30 abstract 198, 1997, Ids #3).

The claims recite an antibody which recognizes human 17-1A antigen on the surface of cells which comprises a human VH and human VL wherein the VH is from unprimed mature human B-lymphocytes and the VL is from a human B-cell repertoire and fragments thereof.

Hoess et al teach antibodies which bind to the 17-1A antigen and the antibodies were from a human library and the scFv were selected to bind to target cells overexpressing the antigen.

The product is claimed in a product by process format wherein the VH and VL chains are derived from a certain source. The VH and VL chains are no different depending on the source of the chains. The B cells would have the VH and the VL chains and as such would not differ whether they were unprimed or not. Therefore the method in which the antibodies were produced is immaterial to their patentability. "Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product I in the product-by-process claim I is the same or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re* Thorpe, 227 USPQ 964, 966 (Fed. Cir. 1985). See also MPEP 2113.

Hoess et al does not specifically isolate an antibody that binds to the antigen on cells but this would have been obvious in view of the teachings.

It would have been prima facie obvious to one of ordinary skill in the art at the time the claimed invention was made to have produced antibodies against the 17-1A antigen on the surface of the cells.

One of ordinary skill in the art would have been motivated to and had a reasonable expectation of success to have produced antibodies against the 17-1A antigen on the surface of the cells because Hoess et al teach generation of human antibodies that selectively recognize diseased cells overexpressing 17-1A surface bound antigens. Thus, it would have been obvious to produce such antibodies.

Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references.

Conclusion

11. No claim is allowed.

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Larry R. Helms, Ph.D, whose telephone number is (571) 272-0832. The examiner can normally be reached on Monday through Friday from 7:00 am to 4:30 pm, with alternate Fridays off. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached at (571) 272-0871.

14. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Fax Center telephone number is 703-872-9306.

Respectfully,

Larry R. Helms Ph.D.

571-272-0832

LARRY R. HELMS, PH.D
PRIMARY EXAMINER